ANPRO-LORATADINE TABLET 10MG

NAME AND STRENGTH OF ACTIVE INDREDIENT(S):
Each tablet contains:
Loratadine……10mg

PRODUCT DESCRIPTION:
A white, scored, flat of oval tablet (7.7 x 5.25mm)

PHARMACODYNAMICS :
Loratadine, the active ingredient is a tricyclic antihistamine with selective, peripheral H_1 – receptor activity. Loratadine has no clinically significant sedative or anticholinergic properties in the majority of the population and when used at the recommended dosage. During long-term treatment there were no clinically significant changes in vital signs, laboratory test values, physical examinations or electrocardiograms. Loratadine has no significant H_2 – receptor activity. It does not inhibit norepinephrine uptake and has practically no influence on cardiovascular function or on intrinsic cardiac pacemaker activity.

PHARMACOKINETICS:
After oral admistration, loratadine is rapidly and well absorbed and undergoes an extensive first pass metabolism, mainly by CYP3A4 and CYP2D6. The major metabolite-desloratadine (DL)-is pharmacologically active and responsible for a large part of the clinical effect. Loratadine and DL achieve maximum plasma concentrations (T_{max}) between 1-1.5 hours and 1.5-3.7 hours after adminstration, respectively.
Increase in plasma concentrations of loratadine has been reported after concomitant use with ketoconazole, erythromycin, and cimetidine in controlled trials, but without clinically significant changes (including electrocardiographic).
Loratadine is highly bound (97% to 99%) and its active metabolite moderately bound (73% to 76%) to plasma proteins.
In healthy subjects, plasma distribution half-lives of loratadine and its active metabolite are approximately 1 and 2 hours, respectively. The mean elimination half-lives in healthy adult subjects were 8.4 hours (range= 3 to 20 hours) for loratadine and 28 hours (range = 8.8 to 92 hours) for the major active metabolite.
Approximately 40% of the dose is excreted in the urine and 42% in the faeces over a 10 day period and mainly in the form of conjugated metabolites. Approximately 27% of the dose is eliminated in the urine during the first 24 hours. Less than 1% of the active substance is excreted unchanged in active form, as loratadine or DL.
The bioavailability parameters of loratadine and of the active metabolite are dose proportional. The pharmacokinetic profile of loratadine and its metabolites is comparable in healthy adult volunteers and in healthy geriatric volunteers.
Concomitant ingestion of food can delay slightly the absorption of loratadine but without influencing the clinical effect.
In patients with chronic renal impairment, both the AUC and peak plasma levels (C_{max}) increased for loratadine and its metabolite as compared to the AUCs and peak plasma levels (C_{max}) of patients with normal renal function. The mean elimination half-lives of loratadine and its metabolite were not significantly different from that observed in normal subjects. Haemodialysis does not have an effect on the pharmacokinetics of loratadine or its active metabolite in subjects with chronic renal impairment.
In patients with chronic alcoholic liver disease, the AUC and peak plasma levels (C_{max}) of loratadine were double while the pharmacokinetic profile of the active metabolite was not significantly changed from that in patients with normal liver function. The elimination half-lives for loratadine and its metabolite were 24 hours and 37 hours, respectively, and increased with increasing severity of liver disease.
Loratadine and its active metabolite are excreted in the breast milk of lactating women.

INDICATION:
Loratadine is indicated for the relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching and burning. Nasal and ocular signs and symptoms are relieved rapidly after oral administration.
Loratadine is also indicated for relief of symptoms and signs of chronic urticaria and other allergic dermatologic disorders.

RECOMMENDED DOSAGE:
Adults and children 12 years of age and over
One tablet (10mg) once daily;
Children 6 to 12 years of age
Body Weight > 30kg – One tablet (10mg) once daily
Body Weight < 30kg – 5mg once daily
Safety and efficacy of Loratadine has not been established in children younger than 2 years of age. Patients with severe liver impairment should be administered a lower intial dose because they may have reduced clearance of loratadine; an initial dose of 5mg once daily, or 10mg every other day is recommended.

ROUTE OF ADMINISTRATION:
Oral

CONTRAINDICATIONS:
Loratadine is contraindicated in patients who are hypersensitivity to the active substance or to any of the excipients in these formulations.

WARNINGS AND PRECAUTIONS:
Loratadine should be administered with caution in patients with severe liver impairment. The administration of Loratadine should be discontinued at least 48 hours before skin tests since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity index.

INTERACTIONS WITH OTHER MEDICAMENTS:
When administered concomitantly with alcohol, loratadine has no potentiating effects a measured by psychomotor performance studies. Potential interaction may occur with all known inhibitors of CYP3A4 and CYP2D6 resulting in elevated levels of loratadine which may cause an increase in adverse events.

PREGNANCY AND LACTATION:
Safe use of loratadine during pregnancy has not been established; therefore, use only if the potential benefit justifies the potential risk to fetus. Since loratadine is excreted in breast milk, a decision should be made whether to discontinue nursing or discontinue the drug.

SIDE EFFECTS:
In paediatric population, children aged 2 through 12 years, common adverse reactions reported in excess of placebo were headache, nervousness and fatigue.
The most frequent adverse reactions in adults and adolescents were somnolence, headache, increased appetite and insomnia. Other adverse reactions reported very rarely during the post-marketing period are listed below.
Immune system disorders
Anaphylaxis
Nervous system disorders
Dizziness
Cardiac disorders
Tachycardia, palpitation
Gastrointestinal disorders
Nausea, dry mouth, gastritis
Hepatobiliary disorders
Abnormal hepatic function
Skin and subcutaneous tissue disorders
Rash, alopecia
General disorders and administration site conditions
Fatigue

SYMTPOMS AND TREATMENT OF OVERDOSAGE:
Overdosage with loratadine increase the occurrence of anticholinergic symptoms. Somnolence, tachycardia and headache have been reported with overdoses. In the event of overdose, general symptomatic and supportive measures are to be instituted and maintained for as long a necessary. Administration of activated charcoal as a slurry with water may be attempted. Gastric lavage may be considered. Loratadine is not removed by haemodialysis and it is not known if loratadine is removed by peritoneal dialysis. Medical monitoring of the patient is to be continued after emergency treatment.

EFFECT ON ABILITY TO DRIVE AND USE MACHINE:
No impairment occurred in patients receiving loratadine. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

PRECLINICAL SAFETY DATA:
Not applicable.

INSTRUCTION FOR USE:
For oral use only.

STORAGE CONDITIONS:
Store below 30ºC in well-closed containers. Protect from light, heat and moisture.
Keep the medicine out of reach of children/ Jauhi dari kanak-kanak.

DOSAGE FORMS AND PACKAGING AVAILABLE:
Pack size: Blister Pack: 50 x10's

NAME AND ADDRESS OF MANUFACTURER / PRODUCT REGISTRATION HOLDER:
MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)
Plot 14, Lebuhraya Kampung Jawa,11900 Bayan Lepas,
Pulau Pinang, Malaysia.

DATE OF REVISION:
04/11/2020